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## CORRECTED NOTICE OF ALLOWANCE AND FEE(S) DUE

23280 7590 03/17/2011  
Davidson, Davidson & Kappel, LLC  
485 7th Avenue  
14th Floor  
New York, NY 10018

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	
DATE MAILED: 03/17/2011	

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/571,184 07/17/2006 David Morton 478.1077 9629

TITLE OF INVENTION: MUCOACTIVE AGENTS FOR TREATING A PULMONARY DISEASE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$0 \$0 \$1510 \$0 00/00/0000

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. NEITHER A NOTICE OF ALLOWANCE NOR A CORRECTED NOTICE OF ALLOWANCE IS A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND ANY PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THE THREE MONTH PERIOD BEGINNING ON THE MAILING DATE OF THE PREVIOUSLY-MAILED NOTICE OF ALLOWANCE AND ENDING ON THE DATE DUE SHOWN ON THIS FORM, OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. MAILING OF THIS CORRECTED NOTICE OF ALLOWANCE DOES NOT CHANGE THE DATE DUE OF THE ISSUE FEE (AND ANY REQUIRED PUBLICATION FEE). IF A REPLY (WITH PAYMENT OF THE ISSUE FEE AND ANY PUBLICATION FEE) WAS FILED IN RESPONSE TO THE PREVIOUSLY-MAILED NOTICE OF ALLOWANCE, THEN NO FURTHER REPLY IS REQUIRED FROM APPLICANT.**

All communications regarding this application must include the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE, unless advised to the contrary.



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## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 264 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 264 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/571,184	MORTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to Applicant's information disclosure statement submitted 2/17/2011.
2.  The allowed claim(s) is/are 1-3,6-8,10,11,13-25 and 30-50.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All    b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 2/17/2011
4.  Examiner's Comment Regarding Requirement for Deposit of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

/Eric S Olson/  
Primary Examiner, Art Unit 1623

**Detailed Action**

This supplemental office action is a response to applicant's information disclosure statement submitted February 17, 2011. This application is a national stage application of PCT/GB04/03932, filed September 15, 2004, which claims priority to foreign applications GB0321611.6, filed June 15, 2003, and GB0327723.3, filed November 28, 2003.

Claims 1-3, 6-8, 10, 11, 13-25, and 30-50 are pending in this application.

Claims 1-3, 6-8, 10, 11, 13-25, and 30-50 as amended are examined on the merits herein.

**Reasons for Allowance**

Applicant's information disclosure statement, submitted February 17, 2011, and the enclosed references, have been fully considered and not found to be the basis for any new grounds of rejection against the claims as previously allowed in the notice of allowance submitted January 4, 2011.

The information disclosure statement contains two correspondences from foreign patent offices. Both documents present grounds of rejection against claims in related applications filed by the Applicant. However, neither document addresses the limitation in the previously allowed claims requiring that the composition used in the claimed method contain 2% w/w or more of leucine. As discussed in the notice of allowance submitted January 4, 2011, Applicant has disclosed that the combination of heparin and 2% or more of leucine, as required by the present claims, produces an unexpected

improvement in the fine particle fraction of the composition, thereby overcoming any *prima facie* case of obviousness for adding 2% or more of leucine to such a composition. As discussed previously, because this effect is specific to the combination of heparin and leucine, references such as WO01/32144, which are generic to a large number of active agents, with no specific teaching of combining heparin and leucine, do not render the claims obvious.

Accordingly, the information disclosure statement submitted February 17, 2011, is not seen to be the basis for any new grounds of rejection, and the claims remain allowable for the reasons previously of record.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Primary Examiner, Art Unit 1623  
2/22/2011